



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,548	12/22/2006	Anders Carlsson	4528-0124PUS2	8478
2292 7590 12/28/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER DANG, IAN D				
ART UNIT 1647		PAPER NUMBER		
NOTIFICATION DATE 12/28/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/590,548

Applicant(s)

CARLSSON ET AL.

Examiner

IAN DANG

Art Unit

1647

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 19, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 19, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 31 August 2009 has been entered in full. Claims 2-14, 16-18, and 20-23 have been cancelled and claims 1 and 19 have been amended. Claims 24 and 25 have been added.

Claims 1, 15, 19, 24, and 25 are under examination.

Specification

The objection made to the specification has been withdrawn in view of the new title reciting "COLLOIDIAL PEPTIDE-GALACTOLIPID COMPLEX IN AQUEOUS SOLUTION" filed on 08/31/2009.

Rejections Withdrawn

35 USC § 102

Applicant's response and arguments filed on 08/31/2009 have overcome the rejection of claims 1 and 19 under 35 USC 102(b) as being anticipated by Engstrom et al. (US Patent 5,151,272; published September 29, 1992; cited as reference AA in the IDS filed 12/13/2006).

At pages 6 and 7 of the response, Applicants indicate that the present invention is directed to colloidal protein-lipid complexes, and Engstrom '272 fails to disclose the colloidal feature. Applicants also note the specification at page 7, lines 16-17, which explains how colloidal systems are thermodynamically stable. In contrast, the compositions of Engstrom '272 specifically encompass liquid crystal systems. Colloids and liquid crystals are discrete, mutually

exclusive systems and, therefore, the subject matter of the present invention is patentably distinct from that of Engstrom '272. The rejection of claims 1 and 19 under 35 USC 102(b) has been withdrawn.

Applicant's response and arguments filed on 08/31/2009 have overcome the rejection of claims 1, 15, and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al. (US Patent 6,306,433; filed 07/22/1998; issued 10/23/2001). At page 7 of the response, Applicants note the disclosure in Andersson '433 wherein its lipid-protein mixtures of 7-25 nm particle size are not colloidal. The rejection of claims 1, 15, and 19 under 35 USC 102(b) has been withdrawn.

New Ground of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 15, 19, and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 9, 11, and 14 of U.S. Patent No. 7,452,864. Although the conflicting claims are not identical, they are not patentably distinct from each other because the peptide-lipid complex in an aqueous solution with the proviso that the peptide is not LL-37 and the medicament comprising an aqueous solution with the proviso that the peptide is not LL-37 of the instant application are not distinct from the pharmaceutical composition comprising an aqueous solution with a peptide containing at least 25 amino acids for the terminal fragment of the peptide LL-37 (SEQ ID NO:1) that include LL-25 to LL-36 recited in claims 6, 9, 11, and 14.

More specifically, claim 1 of the instant application is drawn to a peptide-lipid complex in an aqueous solution, wherein the lipid is a bilayer forming galactolipid material and the weight ratio between the peptide and the galactolipid is 1:5-1:50 with the proviso that the peptide is not LL-37 (SEQ ID NO:1) corresponding to claim 6 of the '864 patent reciting a pharmaceutical composition comprising a peptide comprising a peptide containing at least 25 amino acids for the terminal fragment of the peptide LL-37 (SEQ ID NO:1) and a bilayer forming polar lipid carrier comprising a galactolipid and claim 9 reciting that peptide fragment of composition includes LL-25 to LL-36. Please note that the limitation reciting "a peptide containing at least 25 amino acids for the terminal fragment of the peptide LL-37 (SEQ ID NO:1)" corresponds to the different fragments of LL-37 that are named LL-25 to LL-36 (these LL-37 fragments are displayed at page 4 of the specification for the instant application) and meeting the proviso that the peptide is not LL-37 (SEQ ID NO:1). In addition, claim 1 of the instant application corresponds claim 11 of the '864 patent reciting an aqueous solution, and claim 14 reciting the ratio between the peptide and the bilayer forming polar lipid is 1:10 to 1:50 by weight. Finally, although the claims of the '864 patent do not teach a peptide-lipid complex and a peptide-lipid

complex being colloidal, the pharmaceutical composition recited in claims 6, 9, 11, and 14 would inherently result in peptide-lipid complex and a peptide-lipid complex being colloidal, since the composition recited claim 1 of the instant applications and the one in claims 6, 9, 11, and 14 of the '864 patent are the same.

In addition, claims 19, 24, and 25 of the instant application drawn to a medicament comprising comprising a peptide-lipid complex in an aqueous solution, wherein the lipid is a bilayer forming galactolipid material and the weight ratio between the peptide and the galactolipid is 1:5-1:50 with the proviso that the peptide is not LL-37 (SEQ ID NO:1) corresponds to the recitation of claims 6, 9, 11, and 14 of the '864 patent as recited above. In addition, claim 19 of the instant application recites a pharmaceutical composition comprising a complex between LL-37 and a bilayer-forming galactolipid material corresponding to claim 6 of the '864 patent reciting a pharmaceutical composition comprising a LL-37 peptide and a bilayer forming polar lipid carrier comprising a galactolipid and claim 7 reciting the peptide is LL-37 (SEQ ID NO:1). Please note that the recitation of a "medicament" recited of claims 19 and 24 of the instant application is equivalent to the recitation of "pharmaceutical composition" recited in claim 6 of the '864 patent.

Furthermore, although the claims of the '864 do not recite a complex and the mean size the complexes are below 100 nm, the pharmaceutical composition comprising a peptide comprising a fragment of an amino acid of LL-37 and a bilayer comprising a galactolipid would inherent result in the formation of complexes and complexes with sizes below 100 nm corresponding to claim 19, since the composition recited claim 1 of the instant application is the same as the one recited in claims 6, 7, 9, 11, and 14 of the '864 patent.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
December 16, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647